Message

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Sent: 7/6/2011 6:12:28 PM
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Subject: NEWS UPDATES: EPA Drops Controversial Safety Factors For Acrylonitrile Cancer Estimate (Risk Policy Report)

EPA Drops Controversial Safety Factors For Acrylonitrile Cancer Estimate

Posted: July 1, 2011

EPA is dropping a set of unique safety factors it had crafted for its estimate of the cancer risk associated with the plastic ingredient acrylonitrile and is instead applying a less stringent default approach after the factors the agency had developed relied heavily on studies from a controversial Italian laboratory.

The agency's National Center for Environmental Assessment (NCEA) released its draft Integrated Risk Information System (IRIS) assessment for acrylonitrile, a widespread chemical used in making plastics, synthetic rubbers, surface coatings, adhesives and medical tubing, on June 30 after stalling the draft assessment for a year pending further EPA review of the Ramazzini Institute studies.

EPA is taking public comment on the draft IRIS document through Aug. 29 and will hold an Aug. 10 listening session. *Relevant documents are available on InsideEPA.com.* (*Doc ID: 2368861*)

The risk assessment, when finalized, could be used by the agency to drive a host of new air toxics, water and cleanup standards for the chemical, which is present at several waste sites included on the agency's Superfund National Priorities List.

In its draft assessment, EPA is proposing to tighten its 20-year-old cancer and non-cancer risk estimates, and suggesting a first-time reference dose (RfD), or amount of the substance the agency believes can be ingested daily over a lifetime without adverse effects, for acrylonitrile.

But EPA is sidestepping additional controversy over data generated by the Italian Ramazzini Institute by opting to drop its age dependent adjustment factors (ADAFs), extra safety factors applied to chemicals thought to pose specific cancer risks to children, which would have marked the first time the agency has ever developed data-specific ADAFs tailored to a particular chemical for risk

assessment purposes.
The move weakens the lifetime exposure estimate of the chemical's cancer potency by at least three times.
Instead, EPA is using the default ADAFs outlined in its 2005 "Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens" to predict age-related vulnerability in its calculation of the cancer risks for acrylonitrile, which significantly weakens its estimate of the chemical's cancer causing potency because those factors apply a 1-fold factor to exposed individuals over the age of 16 years, whereas the draft acrylonitrile-specific ADAFs applied 3.6 factor to estimating total lifetime risk.
EPA's supplemental guidance and cancer guidelines require use of a conservative linear modeling approach to estimating cancer risk and application of the ADAFs where it is determined a chemical causes cancer by mutagenic means, or where the carcinogenic mechanism is unknown. The linear modeling is considered more stringent than nonlinear because it assumes there is no safe exposure threshold to the chemical.
The ADAFs are applied to EPA's draft cancer slope factors (CSF), an oral CSF of 5 per milligrams per kilogram per day (mg/kg-day), which tightens its 1991 estimate of oral cancer risk, 5.4E-1 per (mg/kg)/day, and its new inhalation unit risk of 2 x 10-2 per milligrams per cubic meter (mg/m3), revised from the 1991 estimate of 6.8 x 10-5 per micrograms per cubic meter (ug/m3).
EPA decided to stall its draft assessment for acrylonitrile along with ones pending for methanol and the fuel additives methyl tertiary butyl ether (MTBE) and ethyl tert-butyl ether (ETBE) last year after a National Toxicology Program (NTP) review of the Ramazzini cancer data for methanol purportedly showed fewer incidence of cancer in test rodents than the laboratory had initially reported.
But the agency said April 11 it would continue its assessments for those chemicals because the assessment does not heavily rely on the Ramazzini Institute's 1988 *Maltoni et al* cancer studies, avoiding controversy amid the NTP concerns and industry criticisms that the lab's study designs -- which vary a great deal from U.S. methods -- lead to confounding results (*Risk Policy Report,* April 12).
Whereas the majority of U.S. labs tend to use pathogen-free strains of rodents and labs equipped with barriers to keep out pathogens, with the idea of avoiding confounding infections, and limit the studies to two years in duration, the Ramazzini scientists take an approach that does not shield the animals against pathogens and allows them to die naturally, believing their design better mimics human exposure to chemicals.
In its draft IRIS assessment for acrylonitrile, EPA describes the discrepancies between the two labs as "differences of opinion between NTP scientists and the Ramazzini Institute in the diagnosis of certain cancers" in the methanol study.
In crafting the chemical-specific ADAFs, EPA considered two studies, *Maltoni et al* and a 2002 study, *Friedman and Beliles,* which was found to have too small of a number of animals per experimental group to be included in the derivation of the ADAFs.
Because of the NTP concerns, EPA veered away from using the *Maltoni et al* tumor study for crafting the ADAFs, the agency says in its draft assessment, though it is including the Ramazzini study in its support for assuming early-life susceptibility to the chemical. "While these data are considered qualitatively as support for early-life susceptibility, EPA decided not to rely on these data for quantitative purposes."
EPA's default safety factors, however, apply a 10-fold safety margin to exposed individuals younger than two years, and a three-fold factor to children ages two to 16 years, whereas the draft chemical-specific ADAFs applied the 10-fold margin to a much broader age group -- up to 20 years old -- and the 3.6 factor to estimate total lifetime susceptibility.
In a memo to NCEA on EPA's draft assessment for acrylonitrile, Greg Miller, deputy associate director for chemical regulations for the White House Council on Environmental Quality (CEQ) says the agency's decision to use the default ADAFs is appropriate due to the concerns over the Ramazzini data. "Given the limitations of the Ramazzini data and the need to move forward with this

assessment, I support this change and EPA's intention to release the draft for external peer review and public comment."

But in interagency comments from the White House Office of Management and Budget (OMB), officials urge EPA to consider beefing up its rationale for determining a mutagenic mode of action, a finding which results in the more stringent linear approach to the cancer assessment and application of the ADAFs.

"The EPA Cancer guidelines also discuss how evaluation of the mode of action of each tumor is important and thus EPA may want to apply the mode of action framework and discuss how it supports the relevance" of the tumor findings, OMB says. "This analytical approach may help to increase EPA's scientific justification for considering these tumors," the comments say, noting that EPA discusses mode of action for only one type of tumor, forestomach tumors, but includes several other tumor types in its cancer assessment.

But CEQ in its memo appears supportive of EPA's proposed mutagenic mode of action finding and use of the ADAFs in its cancer assessment, saying "This is consistent with EPA guidance."

The draft assessment also included an updated reference concentration (RfC), or estimate of the amount of a chemical EPA estimates can be inhaled daily over a lifetime without adverse effects, of 9 x 10-4 mg/m3, which uses more recent epidemiological studies showing neurobehavioral and reproductive effects and new developmental toxicity data, tightening its previous noncancer risk estimate of 2 x 10-3 mg/m3.

And EPA has crafted a first time RfD of 2 x 10-4 mg/kg/-day based on available animal studies showing increased risk of forestomach lesions, which are comparable to the human endpoint of cell tissue damage in the oral cavity and esophagus. -- *Bridget DiCosmo*

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